Dated: August 27, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–21099 Filed 8–31–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0050]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Importer's Entry Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Importer's Entry Notice'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3792, e-mail: *Elizabeth.Berbakos@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 28, 2009 (74 FR 25554), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0046. The approval expires on August 31, 2012. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: August 26, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–21097 Filed 8–31–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0209] (formerly Docket No. 2007D–0491)

Guidance for Industry: Questions and Answers Regarding the Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Questions and Answers Regarding the Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act.'' The document provides guidance to the dietary supplement industry for complying with the labeling requirements prescribed for dietary supplement manufacturers, packers, and distributors by the Dietary Supplement and Nonprescription Drug Consumer Protection Act (DSNDCPA). Separate guidance on labeling requirements for nonprescription (over-the-counter) human drugs marketed without an approved application, issued by FDA's Center for Drug Evaluation and Research, is announced elsewhere in this issue of the **Federal Register**.

DATES: Submit written or electronic comments on the guidance at any time.

ADDRESSES: Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the guidance to *http://www.regulations.gov*. Submit written requests for single copies of the guidance to the Office of Nutrition, Labeling, and Dietary Supplements (HFS–800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20750. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Vasilios Frankos, Center for Food Safety and Applied Nutrition (HFS–810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2375.

SUPPLEMENTARY INFORMATION:

I. Background

On December 22, 2006, the President signed into law DSNDCPA (Public Law 109–462, 120 Stat. 3469). This law amends the Federal Food, Drug, and Cosmetic Act (the act) with respect to serious adverse event reporting for dietary supplements and nonprescription drugs marketed without an approved application. The law also amended the act to add section 403(y) (21 U.S.C. 343(y)), which requires the label of a dietary supplement marketed in the United States to include a domestic address or domestic telephone number through which the product's manufacturer, packer, or distributor may receive a report of a serious adverse event associated with the dietary supplement.

In the **Federal Register** of January 2, 2008 (73 FR 197), FDA announced the availability of a draft guidance entitled ''Questions and Answers Regarding the Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act.'' In addition to providing guidance for industry on how to comply with the labeling requirements in section 403(y) of the act, the draft guidance stated that FDA intended to begin enforcing the requirements of section 403(y) for dietary supplements labeled on or after January 1, 2009. Although interested parties can comment on any guidance at any time, to ensure that the agency would have the opportunity to consider comments on the draft guidance before it began work on the final version, FDA requested that interested parties submit comments by March 3, 2008. On December 11, 2008 (73 FR 75438), FDA announced the availability of a revised version of the draft guidance document to notify the dietary supplement industry and other members of the public that it intended to exercise enforcement discretion with regard to the labeling requirements of section 403(y) of the act for an additional 1-year period (i.e., for dietary supplements labeled before January 1, 2010) because the agency was still in the process of reviewing the comments and finalizing the guidance. The agency has now completed its review and evaluation of the comments received and has modified the guidance where appropriate.

The guidance contains questions and answers relating to the labeling requirements in section 403(y) of the act and provides guidance to industry on the following topics: (1) The meaning of ''domestic address'' for purposes of the

labeling requirements of section 403(y) of the act; (2) FDA's recommendation for the use of an introductory statement before the domestic address or domestic telephone number that is required to appear on the product label under section 403(y) of the act; and (3) that FDA intends to begin enforcing the labeling requirements of section 403(y) of the act for products labeled on or after September 30, 2010.

FDA is issuing this guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the labeling of dietary supplements as required by the DSNDCPA. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in this guidance were approved under OMB control no. 0910–0642.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at *http://www.cfsan.fda.gov/guidance.html*.

Dated: August 26, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–21094 Filed 8–31–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0429] (formerly Docket No. 2007D–0496]

Guidance for Industry on Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act: Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act: Questions and Answers.'' This guidance is intended to assist industry in complying with the labeling requirements for nonprescription (over-the-counter (OTC)) human drugs marketed without an approved application established by the Dietary Supplement and Nonprescription Drug Consumer Protection Act (DSNDCPA). Separate guidance, issued by the Center for Food Safety and Applied Nutrition on complying with the labeling requirements for dietary supplements, is announced elsewhere in this issue of the **Federal Register**.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, rm. 2201, Rockville, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Walter Ellenberg, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5488, Silver Spring, MD 20993–0002, 301–796–2090.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act: Questions and Answers.'' On December 22, 2006, the President signed into law DSNDCPA (Public Law 109–462, 120 Stat. 3469). This law amends the Federal Food, Drug, and Cosmetic Act (the act) with respect to serious adverse event reporting for dietary supplements and nonprescription drugs marketed without an approved application. The law also amended the act to add section 502(x) (21 U.S.C. 352(x)), which requires the label of an OTC drug product marketed in the United States without an approved application to include a domestic address or domestic telephone number through which the product's manufacturer, packer, or distributor may receive reports of serious adverse events associated with its use.

In the **Federal Register** of January 2, 2008 (73 FR 196), FDA announced the availability of a draft version of the guidance containing questions and answers relating to the new labeling requirements under Public Law 109–462 for OTC drugs marketed without an approved application. In addition to providing guidance for industry on how to comply with the labeling requirements in section 502(x) of the act, the draft guidance stated that FDA intended to begin enforcing the requirements of section 502(x) for OTC human drugs marketed without an approved application labeled on or after January 1, 2009. Although interested parties can comment on any guidance at any time, to ensure that the agency would have the opportunity to consider comments on the draft guidance before beginning work on the final version of the guidance, FDA requested that interested parties submit comments by March 3, 2008. On December 11, 2008 (73 FR 75436), FDA announced the availability of a revised draft guidance to notify industry and other members of the public that it intended to exercise enforcement discretion with regard to the labeling requirements of section 502(x) of the act for an additional 1-year period (i.e., for OTC drug products marketed without an approved